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MP14-02 THE NATURAL HISTORY OF MEN ON ACTIVE SURVEILLANCE WITH LOW-RISK PROSTATE CANCER AT A SAFETY-NET, COUNTY HOSPITAL

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MP14-01

THE UNCOUPLING OF DIAGNOSIS AND IMMEDIATE TREATMENT IN VERY LOW AND LOW RISK PROSTATE CANCER: A NATIONAL PERSPECTIVE

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INTRODUCTION AND OBJECTIVES: A critical means of reducing the morbidity associated with screening for prostate cancer (CaP) is uncoupling diagnosis from treatment. In some men, treatment risks may outweigh benefits. We sought to understand the current treatment landscape of men with very low or low risk (VLoLR) CaP and to determine factors associated with receiving treatment in a contemporary national cohort.

METHODS: Using the National Cancer Database for the years 2010-2013, men with CaP were categorized into risk groups using NCCN criteria by PSA, Gleason score, cT stage, and number of positive cores. In men with VLoLR CaP, radical prostatectomy (RP), radiotherapy (RT), or androgen deprivation therapy (ADT) within 1 year was considered immediate treatment. Men managed with active surveillance (AS), watchful waiting (WW), or no treatment (NoTx) were also analyzed. Treatment patterns by age, comorbidities, and diagnosis year were assessed. Logistic regression modeling was used to determine factors associated with higher likelihood of receiving any treatment.

RESULTS: Of 448,810 men diagnosed with CaP, 46,290 (11.9%) had very low risk and 60,122 (15.5%) had low risk CaP. In this combined VLoLR Cap cohort, overall median age was 62 with 34.6% of men being older than 65. Overall, 74.8% of men with VLoLR CaP received primary treatment within 1 year of diagnosis. Primary treatment rates declined over time while management with AS/WW/NoTx increased (Figure 1). In men >65 with VLoLR CaP, 28.9% had RP, 35.9% got RT, and 19.2% had AS/WW/NoTx. In men >75, only 5.3% received RP, 39.9% got RT, and 25.4% had AS/WW/NoTx. Age >65 (OR 0.55 95% CI 0.53-0.57), being treated at an academic center (OR 0.68, 95% CI 0.66-0.71), and progressive years after 2010 were associated with lower odds of treatment (Table 1).

CONCLUSIONS: Significant numbers of men with VLoLR CaP underwent primary treatment during 2010-2013, including older men, in whom there is no established benefit to treatment. However, a trend toward more conservative management is apparent.

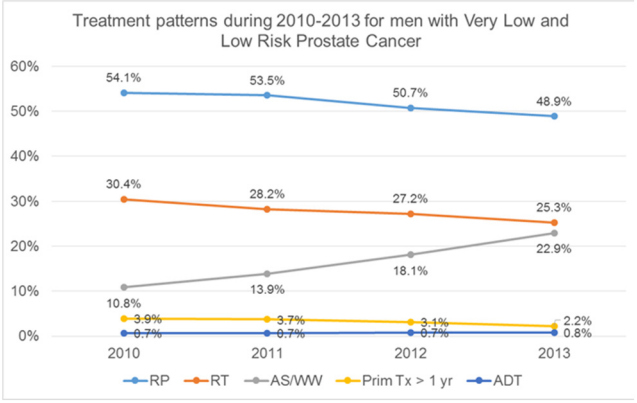

Table 1: Binomial logistic regression analysis assessing factors associated with receiving treatment for very low or low risk prostate cancer within 1 year during year 2010-2013

	Odds Ratio	Lower 95% CI	Upper 95% CI	p-value
Age Group				
Under 65	1.00			
65 and older	0.55	0.53	0.57	<0.01
Charlson-Deyo Score				
0-1	1.00			
2+	0.99	0.88	1.12	0.93
Race				
White	1.00			
Black	0.94	0.89	0.99	0.01
Hispanic/Spanish	0.84	0.77	0.92	<0.01
Asian	0.76	0.67	0.85	<0.01
Other/Unknown	1.01	0.94	1.08	0.77
Insurance Status				
Uninsured/Medicaid/Unknown	0.58	0.54	0.63	<0.01
Medicare	1.00			
Private Insurance	1.09	1.04	1.14	<0.01
Hospital Setting				
Community	1.00			
Academic	0.68	0.66	0.71	<0.01
NCCN Risk Category				
Very low	1.00			
Low	2.17	2.10	2.24	<0.01
Year of Diagnosis				
2010	1.00			
2011	0.82	0.78	0.85	<0.01
2012	0.63	0.60	0.66	<0.01
2013	0.50	0.48	0.53	<0.01

Source of Funding: none

MP14-02

THE NATURAL HISTORY OF MEN ON ACTIVE SURVEILLANCE WITH LOW-RISK PROSTATE CANCER AT A SAFETY-NET, COUNTY HOSPITAL

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INTRODUCTION AND OBJECTIVES: Health care delivery to vulnerable and uninsured patients is challenging due to social and economic barriers. For men with low-risk prostate cancer (PCa) on active surveillance (AS), patient compliance, follow up, and access to care are essential for favorable cancer outcomes. Our primary objective is to characterize demographic, disease and cancer outcomes of men on AS at a safety-net hospital and characterize those who were loss to follow-up (LTFU).

METHODS: From January 2004 to November 2014, 104 men at Zuckerberg San Francisco General (ZSFG) with low-risk PCa were followed with AS. Criteria for AS has evolved over time; however, patients with diagnostic PSA 10ng/mL or less, clinical stage T1/2, biopsy Gleason grade 3+3 or 3+4, 33% or fewer positive cores and 50% or less tumor in any single core were eligible for AS. Men were longitudinally followed with a PSA and/or DRE every 3-6 months and repeat prostate biopsy every 1-2 years. Clinical staging and grading were based on a physical exam and at least a 12-core biopsy respectively. LTFU was defined as failure to contact patients with three phone calls or any urology visit recorded within 18 months from a prior visit or biopsy. A secondary chart review was performed with EPIC Systems© CareEverywhere which allows access to non-ZSFG institutions to confirm patients were truly LTFU.

RESULTS: Among the 104 men on AS at ZSFG, the median age at diagnosis of PCa was 61.5 years (range: 44-81). The median follow-up time period was 29 months (0-186 months) during which 18 men were LTFU and 48 remained on surveillance. Men who remained on AS underwent a median of 7 (1-21) serum PSA measurements and an average of 2 prostate biopsies (1-5). In total, 22 (20.6%) men had definitive treatment with the median time from diagnosis to active treatment being 26 (2-87) months. Radiation therapy was more common that radical prostatectomy (12.5% versus 7.7%). There was one prostate cancer-related death and three non-cancer deaths. Kaplan-Meir curve analysis demonstrates that initial adherence to AS is poor; however as time progresses, adherence increases as those patients committed to early surveillance continue with follow-up.

CONCLUSIONS: AS for low-risk prostate cancer is challenging among a vulnerable population receiving care in a safety-net hospital, as rates of LTFU were high. Our findings suggest the need for an AS program to improve adherence and follow-up among vulnerable and underserved populations.

Source of Funding: Alafi Foundation

MP14-03

HIGHER CHOLESTEROL IS LINKED WITH INCREASED RISK OF HIGH-GRADE PROSTATE CANCER: RESULTS FROM THE REDUCE STUDY

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INTRODUCTION AND OBJECTIVES: Given the prevalence of prostate cancer (PC) and hypercholesterolemia, multiple studies have examined the link between these two conditions with mixed results. These findings may be influenced by studies showing a correlation between higher cholesterol and higher PSA, introducing a bias that may impact the rate of prostate biopsy and cancer detection thereby making high cholesterol appear to be correlated with PC risk. We tested the association between serum lipids and PC in a post-hoc analysis of the REDUCE study, in which subjects underwent study mandated biopsies regardless of PSA, mitigating any bias due to PSA.

METHODS: REDUCE was a 4 year multi-center study testing the effect of dutasteride on PC risk in men with a PSA of 2.5-10.0 ng/mL and a negative pre-enrollment biopsy. As part of the study protocol subjects were required to undergo study-mandated biopsies. The associations between baseline serum cholesterol, low-density lipoprotein cholesterol (LDL) and high-density lipoprotein cholesterol (HDL) with overall PC risk and disease grade (Gleason 2-6 vs. 7-10) at the 2-year biopsy was examined with logistic and multinomial logistic regression, adjusted for baseline covariates. Continuous lipid levels were presented in 10 mg/dL increments to help interpret hazard ratios. We excluded men taking statins.

RESULTS: 4,904 subjects not taking statins were included. Elevated serum cholesterol was associated with a higher risk of high-grade PC diagnosis on multivariable analysis (OR 1.23, $p=0.008$), though no association was seen between overall or low-grade PC risk ($p>0.137$). No association was seen between serum LDL and overall risk of PC or low- or high-grade disease ($p>0.138$). In contrast, elevated serum HDL was associated with a higher risk of overall PC risk (OR 1.34, $p=0.028$) and high-grade PC risk (OR 1.74, $p=0.013$) on multivariable analysis.

CONCLUSIONS: In post hoc analysis of REDUCE, both elevated cholesterol and elevated HDL were associated with increased high-grade PC risk. These data support the hypothesis that high cholesterol is linked with aggressive PC. Given recent data questioning the role of HDL as a cardioprotective factor (Ko et al, J Am College of Cardiology, 2016) and a meta-analysis showing drugs that increase HDL do not reduce cardiovascular risk (Keene et al, BMJ 2014), further study is needed to better understand the link between high HDL and increased PC risk.

Source of Funding: Supported by GlaxoSmithKline and NIH 1K24CA160653

MP14-04

CARDIOVASCULAR DISEASE CHARACTERISTICS OF NEWLY DIAGNOSED PROSTATE CANCER PATIENTS: FINDINGS FROM THE PILOT PHASE OF RADICAL PC: A PROSPECTIVE STUDY OF CARDIOVASCULAR DISEASE IN MEN WITH PROSTATE CANCER

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INTRODUCTION AND OBJECTIVES: Administrative registries suggest that cardiovascular (CV) disease develops frequently in men with prostate cancer (PC). Known CV risk factors, such as hypertension, dyslipidemia, and obesity may account for some of the risk, however PC-specific factors, including androgen deprivation therapy (ADT) may also play a role. The goals of RADICAL PC are to identify the incidence and major determinants of CV disease, and to evaluate whether systematic CV risk factor modification reduces adverse CV events in men with PC. We report the findings for the pilot phase of this study.

METHODS: RADICAL PC recruits consecutive men with a new diagnosis of PC or commencing ADT for the 1st time. Those who do not see a cardiologist annually are randomized in an open manner to receive a CV risk factor intervention (aspirin, statin, blood pressure-lowering to a target systolic of 130mmHg, and standardized exercise and dietary counseling). Those not eligible for randomization are followed to provide a representative sample. At least 6000 men will be recruited and followed for an average of 3 years. Renal function, lipids, and HbA1c will be measured serially. The primary endpoint is the composite of CV death, myocardial infarction, stroke, heart failure, or arterial revascularization. Fisher's exact test and ANOVA test were used for categorical and normally distributed continuous variables comparisons respectively.

RESULTS: The characteristics of the first 421 participants, from 3 Canadian sites, are presented. Of these, 334 were newly diagnosed and 87 were receiving ADT for the 1st time, 25 had metastatic disease and 62 were undergoing radiotherapy. Of all participants, 56% have been randomized, and the remainders are undergoing passive follow up. 41% of the patients had hypertension and of the 246 participants with no known hypertension, additional 31% had blood pressure in the hypertensive range. 17% of the patients are diabetic, 55% are current or previous smokers and 81% are overweight (45%) or obese (36%). A third of the patients are on statins and a third take ASA. Patients who are commencing on ADT are older (67+/-8.4 vs. 71+/-8.3 years $p<0.0001$) and have higher prevalence of preexisting coronary artery disease (11% vs. 20% $p=0.003$) compared to those who have no indication for ADT.

CONCLUSIONS: Pre-established cardiovascular disease and its risk factors are very common in newly diagnosed prostate cancer patients. The baseline characteristics of patients who are planned to initiate ADT may place them in a higher CVS risk compared to the general PC patient population.

Source of Funding: PROSTATE CANCER CANADA
Hamilton Health Sciences RFA strategic initiative

MP14-05

THE ASSOCIATION OF AGE WITH PERIOPERATIVE MORBIDITY AND MORTALITY AMONG PATIENTS UNDERGOING RADICAL PROSTATECTOMY

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INTRODUCTION AND OBJECTIVES: Older age has been considered a relative contraindication to radical prostatectomy (RP) in men who are otherwise candidates for definitive local therapy for prostate cancer. However, there are limited data regarding the association of age with perioperative outcomes following RP, which is particularly relevant given increased life expectancy in the United States. We therefore examined the association of age with perioperative outcomes among men undergoing RP to more fully inform risk-assessment and management.